



2016 CHAPTER 18

PART 8

RESEARCH

Approved research projects

Approval of research projects

134.—(1) The appropriate body may approve a research project for the purposes of this Part only if it is satisfied that the following requirements will be met in relation to research carried out as part of the project on, or in relation to, a person who is 16 or over and lacks capacity to consent to taking part in the project (“P”).

(2) The research must be connected with—

- (a) an impairing condition affecting P; or
- (b) its treatment.

(3) There must be reasonable grounds for believing that research of comparable effectiveness cannot be carried out if the project has to be confined to, or relate only to, persons who have capacity to consent to taking part in it.

(4) The research must—

- (a) have the potential to benefit P without imposing on P a burden that is disproportionate to the potential benefit to P; or
- (b) be intended to provide knowledge of the causes or treatment of, or of the care of persons affected by, the same or a similar condition.

(5) If the research falls within paragraph (b) of subsection (4) but not within paragraph (a), there must be reasonable grounds for believing—

Changes to legislation: *Mental Capacity Act (Northern Ireland) 2016, Section 134 is up to date with all changes known to be in force on or before 25 July 2024. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes*

- (a) that the risk to P from taking part in the project is likely to be negligible;
and
- (b) that nothing done to, or in relation to, P as part of the project will—
 - (i) interfere with P's freedom of action or privacy in a significant way; or
 - (ii) be unduly invasive or restrictive.

(6) Without prejudice to subsection (5), there must be reasonable grounds for believing that no serious intervention will be carried out in respect of P as part of the project unless the intervention is one that could lawfully be carried out in respect of P if it were not part of the project (for example, because the conditions of Part 2 are met).

(7) There must be reasonable arrangements in place for ensuring that the requirements of sections 135 to 137 will be met.

(8) In this section—

“impairing condition” means a condition which is (or may be) attributable to, or which causes or contributes to (or may cause or contribute to), an impairment of, or a disturbance in the functioning of, the mind or brain;

“serious intervention” is to be read in accordance with section 63.

Commencement Information

- II** S. 134 in operation at 1.10.2019 for specified purposes by S.R. 2019/163, art. 2(1), Sch. Pt. 1 (with art. 3) (as amended by S.R. 2019/190, art. 2)

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Changes and effects yet to be applied to the whole Act associated Parts and Chapters:

Whole provisions yet to be inserted into this Act (including any effects on those provisions):

- s. 285(2)(a)-(c) substituted for s. 285(2)(a)(b) by [2022 c. 18 \(N.I.\) Sch. 3 para. 77\(b\)](#)